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09/597,608 06/20/00 NGAI

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RICHARD ARON OSMAN
SCIENCE AND TECHNOLOGY LAW GROUP
75 DENISE DRIVE
HILLSBOROUGH CA 94010

EXAMINER

TAYLOR, J	
ART UNIT	PAPER NUMBER

1655
DATE MAILED:

9
04/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/597,608

Applicant(s)

NGAI ET AL.

Examiner

Janell Taylor Cleveland

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-18 is/are allowed.
- 6) ☒ Claim(s) 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Response to Request for Reconsideration

1. The following Office Action is in response to the request for reconsideration received March 22, 2001. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Following the rejection is a response to arguments.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Catalog, 1995, page 109.

The claim is drawn to a kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1, and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides.

Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Stratagene. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended

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use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art.

Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers and buffer, and instructions, among other things. Therefore, all of the limitations of the instant claim are anticipated by Stratagene.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stratagene in view of Serafini et al. in view of Hampson et al. (USPN 5,591,575).

Claim 20 depends from claim 19, and comprises premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides.

Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers, buffer, and instructions (page 161).

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Stratagene does not teach the use of biotinylated primers and streptavidin beads, or polyadenyl transferase, or DNA pol I.

Serafini et al. teach polyadenyltransferase and DNA polymerase (Cols. 3-4).

Hampson et al. teach biotinylated primer and streptavidin beads (claim 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the kit of Stratagene by adding biotinylated primers and streptavidin beads, as well as polyadenyl transferase and DNA pol I. This is because it was well known in the art at the time of the invention that biotinylated primers and streptavidin beads were very effective in capturing and identifying an amplified nucleic acid. It would also have been obvious to add polyadenyl transferase and DNA pol I because it was well known in the art at the time of the invention that polyadenyl transferase was useful for adding poly(A) sequence, and DNA polymerase was necessary for amplification. All of these items would have been useful in a kit because they all had well known uses in the art.

Summary

Claim 19 is rejected under 35 USC 102(b). Claim 20 is rejected under 35 USC 103(a). Claims 1-18 are free of the prior art and are allowable.

Response to Arguments

5. Applicant's arguments filed March 22, 2001 have been fully considered but they are not persuasive. First, Applicant asserts that "the term 'patentable weight' is legally meaningless." However, in the case of *In re Schreiber*, 44 USPQ2d 1429, decided October 23, 1997, the term "patentable weight" is referred to numerous times. It is

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therefore submitted that the term has legal meaning, which has been recognized by the courts. Secondly, in regards to the reference of *In re Haller*, Applicant states that the citation of this case was improper and does not support the examiner's position.

However, *In re Haller* states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful ~~but~~ and involve ~~the~~ invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. Thirdly, Applicant argues that in *In re Gulack*, the Federal Circuit reversed a Board contention that printed matter could not impart patentability. However, in the case of *In re Gulack*, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional absent the printed instructions for use. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture.

Intended used does not impart patentable weight to a product. See MPEP 2111.03:

Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must

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use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the claims are drawn to a kit comprising instructions, and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides. The intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

Lastly, Applicant has submitted that the rejection of claims 19 and 20 was inappropriate because "hundreds of patents issued in the past few years that clearly rely on the printed matter limitation." However, it is not clear from the examples that the instructions are the component being relied upon to impart patentability, and not another component of the kit. For example, in US 6,177,407, a kit is claimed in claim 2, which comprises multiple SEQ ID NOS as well as instructions. It is asserted that in this case, the SEQ ID NOS are what imparts patentability to the claim, and not the instructions.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or

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305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

April 18, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

4/20/01